NOV 2 1 2000

K002649

**Attachment 7**

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the SLP Diode Array Laser System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

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| Applicant: | Palomar Medical Technologies, Inc. |
| Address: | 82 Cambridge St.<br>Burlington, MA 01803 |
| Contact Person: | Marcy Moore |
| Telephone: | 919-363-2432 |
| Preparation Date: | August 22, 2000 |
| Device Trade Name: | Aramis Dermatologic Laser |
| Common Name: | Aramis Dermatologic Laser |
| Classification Name: | Laser surgical instrument for use in General and Plastic Surgery and in Dermatology<br>(see: 21 CFR 878-4810).<br>Product Code: GEX<br>Panel: 79 |
| Legally-Marketed Predicate Device: | Zeiss Opmilase 144 (K933322; K932376)<br>New Star Model 130 (K962791) |
| System Description: | The Aramis Dermatologic Laser is an Er-glass 1.54 μm system. The complete system consists of a laser unit, cooler, a footswitch, and a handpiece. The handpiece tip is gas-cooled to provide active skin cooling. Laser parameters and other system features are controlled from the touch-buttons on top of the laser unit, which provides an interface to the system computer. |

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| Intended Use of the Device: | The Aramis Dermatologic Laser system is indicated for incision/excision, ablation, and coagulation (homeostasis) of soft tissue. The Aramis Laser is also indicated for the photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins) and the treatment of benign pigmented lesions. |
| Performance Data: | The differences in the specifications of the laser and the predicate device do not result in different performance or raise new questions of safety or efficacy. |
| Conclusion: | Based on the foregoing, the Aramis Laser System is substantially equivalent to the legally-marketed claimed predicate device. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Palomar Medical Technologies, Inc.
c/o Marcy Moore
Manager of Clinical Studies
131 Kelekent Lane
Cary, North Carolina 27511

Re: K002649
Trade Name: Aramis Dermatologic Laser
Regulatory Class: II
Product Code: GEX
Dated: August 22, 2000
Received: August 24, 2000

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATION FOR USE STATEMENT

510(K) Number: Pending K002649

Device Name: Aramis Dermatologic Laser

Indications for Use:

The Aramis Dermatologic Laser system is indicated for incision/excision, ablation, and coagulation (homeostasis) of soft tissue. The Aramis Laser is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins).

(Please do not write below this line - Continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002649